APR 2 5 2001

K010578

ATTACHMENT F

510(k) SUMMARY

The Summary of Safety and Effectiveness on the TAGA Velocity Humidifier reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant **Telephone** **Facsimile**	Gary Austin TAGA Medical Technologies, Inc. 7561 Tyler Road, Unit 8 Mentor, Ohio 44060 440/953-9605 440/953-9602
Date	April 18, 2001
Name	TAGA Velocity Passover Humidifier
Classification	Respiratory gas humidifier, 21 CFR 868.5450
Predicate:	Rescare, Inc. (Corporate Name changed to ResMed) Sullivan Passover Humidifer K950582, market clearance date September 15, 1995; and Respironics, Inc. Oasis Humidifier K964653, market clearance date February 14, 1997
Description	The TAGA Velocity Passover Humidifier is a plastic housing comprised of two (2) halves permanently joined to form an enclosed reservoir. The reservoir has two ports, an inlet and an outlet, on the upper portion, both being 22 mm conical connectors, which allow for the connection of commonly used respiratory CPAP flexible tubing. The inlet and outlet port are clearly identified on the device. The inlet port is typically attached to the pressure generating CPAP unit by means of a short piece (12" to 24") of tubing that is supplied with the humidifier. The air entering the humidifier is directed over the surface of the water in the basin through a series of baffles. The design intent of the baffles shape and placement is to create turbulence in the airflow over the water surface. The baffles also create an eddy effect, which in turn increase the duration that the air is exposed and travels across the surface of the water. The combination of both of these effects maximizes the evaporation process thereby elevating the humidity level of the gas before exiting the device. The air exits the device through the outlet port into a second piece of tubing supplied by the user that is connected the patients' mask. The humidifier is filled with distilled or sterile water through either the inlet or outlet ports with the unit held in an upright position. The humidifier has a window with markings to allow the user to fill with the appropriate volume. The unit is manufactured out of a transparent plastic that allows the user to visually verify the volume level at all times. The volume of water is sufficient to provide 10 hours minimum use at 70 °F and 25% RH ambient conditions and a patient flow rate of 90 LPM. The humidifier is filled only when removed from the CPAP system. The humidifier is used in a horizontal position and will act as a base for most marketed CPAP systems. This feature ensures that the water level is below the outlet port on the CPAP system to eliminate the potential hazard of water reaching any CPAP electrical components.

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Family of TAGA Velocity Humidifiers reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Description continued	The humidifier's moisture gain output exceeds 10mg H_2O/L as required by ASTM F1690-96 and ISO 8185:1997. The maximum pressure drop throughout the range of flow rates does not exceed 2kPa per ASTM F1690-96 and ISO 8185:1997. The Velocity humidifier will be cleaned daily by hand washing with a mild dish washing and warm water solution and weekly by soaking in a 25% vinegar/water solution for 30 minutes, both followed by a clean water rinse.
Intended Use	The TAGA Velocity humidifier is a respiratory Continuous Positive Airway Pressure (CPAP) accessory intended to add moisture to the airstream gases for administration to the patient. The humidifier increases the vapor content of the air as it passes through the device (passover) and is directed by the array of baffles over the surface of a body of water. The humidifier can be used with standard CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have bi-level or automatic pressure titration capabilities.
Warning:	• Disconnect the air tubes prior to cleaning, water entering the CPAP unit may result in electric shock hazard or damage to the CPAP unit. • Do not use bleach or chlorine based solutions to clean the humidifier or tubing. • The humidifier is for single-patient use only. • For use with Nasal CPAP flow generators only. • The humidifier can be used with CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have bi-level or automatic pressure titration capabilities.
Caution:	• Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. • Do not expose the tubing to direct sunlight as it may deteriorate over time. • Do not mix the solution of vinegar with any disinfectants to clean the humidifier or tubing. • Replace the humidifier if any sign of damage to the chamber or leaking appears.
Technological Characteristics	AAMI TIR No. 12 – 1994; Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. Low Level Disinfection. Pressure Range: 3 – 20 cm H_2O Relative Humidity Output: > 25% Operating Temperature: 5° to 40 ° C Storage Temperature: -20° to 60 ° C Reservoir Capacity: 600 ml Operating Duration: 10 Hours @ 70° F, 25% RH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2001

Mr. Gary Austin
Vice President of Engineering & Research/Development
Taga Medical Technologies, Inc.
7561 Tyler Blvd., Unit 8
Mentor, OH 44060

Re: K010578
TAGA Velocity Passover Humidifier Unit
Regulation Number: 21 CFR 868.5450
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: February 23, 2001
Received: February 27, 2001

Dear Mr. Austin:

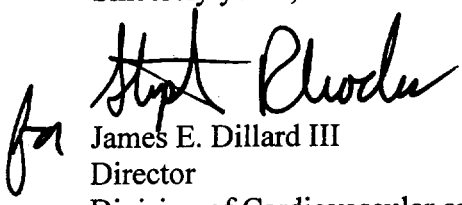
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT B

510(k) Number (if known): K010578

Device Name: TAGA Velocity Passover Humidifier

Indications For Use:

The TAGA Velocity Passover Humidifier is a respiratory Continuous Positive Airway Pressure (CPAP) accessory intended to add moisture to the airstream's gases for administration to the patient. The humidifier increases the vapor content of the air as it passes through the device (passover) and is directed by the array of baffles over the surface of a body of water. The TAGA Velocity™ Passover Humidifier can be used with standard CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have bi-level or automatic pressure titration capabilities.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010578

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)